The effect of physical, social and psychological factors on drug compliance in patients with mild hypertension

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Background. In patients with hypertension non-compliance with drug treatment is between 15 to 54%, and has been recognised as a relevant contributor to the burden of cardiovascular morbidity. Up to 92% of patients experience unpleasant symptoms with their condition and, particularly in these patients, the symptoms experienced may enhance compliance.
Objective. To simultaneously assess the effects of physical, social and psychological factors on non-compliance.
Methods. Patients with mild hypertension despite drug treatment, from the departments of cardiology and internal medicine, were requested to answer a self-administered questionnaire addressing the presence of physical symptoms as well as psychosocial factors. The questionnaire was based on previously used test batteries and consisted of two lists of physical complaints and four lists addressing the four domains of planned behaviour regarding medical non-adherence according to Baron and Byrne. These domains mainly assess psychosocial factors. Each list consisted of three or more items and each item was scored on five- to seven-point scales. Mean scores were used for assessment. The lists were also separately assessed for internal consistency and reliability using Cronbach's alphas. One-way analysis of variance and multivariate analysis of variance (MANOVA) with compliance as outcome variable and the physical, social and psychological variables as indicator variables were used for data analysis. MANOVA was adjusted for multiple testing.
Results. Many patients experienced physical symptoms due to hypertension, such as tiredness (31%), hot flushes (28%), headache (24%), reduced daily life energy (23%), palpitations (22%), with 95% confidence intervals between 16 to 38%. Scores for physical symptoms and social factors did not differ between self-reported adherers (n=165) and non-adherers (n=11). However, the score for psychological factors was significantly larger in the adherers than in the non-adherers, 5.05 versus 3.06, $p<0.018$. The MANOVA showed a significant overall difference between the adherers and non-adherers in the data at $p<0.012$, which was mainly due to the score for psychological factors.
Conclusion. The effect of physical symptoms on non-compliance in mildly hypertensive patients is negligible. So is the effect of social factors. Psychological factors such as lacking a sense of guilt, regret and shame are major determinants of non-compliance. Physicians may play an educational role in improving their patients' compliance by addressing these determinants. We should add that the conclusions should be made with reservations, given the small number of non-adherers in our sample. (*Neth Heart J* 2008;16:197-200.)

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In patients with hypertension non-compliance with drug treatment has been shown to be between 15 to 54%, and has been recognised as a relevant contributor to the burden of cardiovascular morbidity.[1-4] Several

explanations for non-compliance can be given. For example, up to 92% of patients experience unpleasant symptoms of their condition[5-7] and, particularly in these patients, experienced symptoms may enhance compliance. In contrast, hypertension is considered a condition without symptoms,[8,9] and this, in addition to psychological factors such as lack of regret or shame, may enhance non-compliance. To date no report has simultaneously assessed the effects of physical, social and psychological factors on non-compliance. Non-compliant patients will be compared with their compliant counterparts for the presence of the above factors using a battery of previously applied questionnaires. Non-compliance of patients with hypertension is of major concern to cardiologists and internists. We hope the current report will be helpful when dealing with these patients.

Methods

In the period between June 2006 and June 2007, 450 subsequent patients visiting the outpatient clinics of the cardiology departments of the Martini Hospital Groningen, the Regional Hospital Hengelo, and the Zuiderzee Hospital Lelystad, as well as the department of internal medicine of the Martini Hospital Groningen, were invited to participate if, according to their cardiologists or internists, they suffered from persistent mild hypertension (diastolic blood pressure between 90 and 100 mmHg and systolic blood pressure between 140 and 170 mmHg) despite drug treatment.

A self-administered questionnaire was used to assess the patients for (1) experienced physical symptoms that they thought were due to hypertension, (2) numbers of daily emotional symptoms and situations that they believed would increase their blood pressure, and (3) scores of certainty of this belief, on a scale of one to six points. The list of physical and emotional symptoms and situations was based on prior publications assessing the relationship between physical symptoms and the presence of hypertension, including the studies by Brondolo et al.,[10] Meyer et al.,[5] Fahrenberg et al.,[9] Bauman and Leventhal,[6] Cantillon et al.[7] and Lau et al.[11] The patients were assessed for social and psychological factors using a questionnaire based on Baron and Byrne's questionnaire[12] addressing four domains of planned behaviour regarding medical non-adherence: (1) difficulties experienced with being compliant, (2) social factors causing non-compliance, (3) time factors causing non-compliance, (4) feeling of dissatisfaction and guilt due to non-compliance. These four domains consisted of three to six items and were scored on five- to seven-point scales. Mean scores were used. Compliance was assessed using three items on seven-point scales.

Statistical analysis

Although all of the questionnaires from the above test battery have been successfully employed in the past we considered it a matter of course to assess the internal consistency of every factor and domain by calculating Cronbach's alpha prior to data analysis. It has a maximal value of 1.0 whereas a value above 0.70 is recommended to ensure acceptable reliability. For the physical symptoms, mean scores of daily emotional symptoms and situations and their 95% confidence intervals were calculated. To assess the effect of the factors and domains overall mean scores in non-compliance and compliance were compared with one another using one-way analysis of variance (ANOVA) with factors and domains as indicator variables and compliance status as outcome variable. Indicator variables producing a p value <0.15 were subsequently included in a multivariate analysis of variance (MANOVA) to assess whether a significant effect remained in an overall assessment of the data. The indicator variables included in the MANOVA were adjusted for multiple testing using the Games- Howell procedure. One-way ANOVA assumes equal variances of treatment groups. To test the appropriateness of this assumption Levene's test was performed. Statistical significance level was set at $p<0.05$, a trend to statistical significance at $0.05<p<0.15$.

Results

A total of 176 patients completed the study. Their characteristics are shown in table 1. The questionnaire was adequately completed by all of the patients. Table 2 shows that many patients experienced physical symptoms they thought would be due to their hypertension. Particularly, tiredness (31%), sudden hot flushes (28%), headache (24%), reduced daily life energy (23%) and palpitations (22%) scored relatively highly. Table 3 shows that many patients also believed that daily emotional symptoms and situations increased their

Table 1. Patients' characteristics.

	Number	Age (years)		Patients with BP device	General health score*
		Mean	SD	N	Mean
Male	92	61.50	12.54	45	4.41
Female	84	62.60	14.33	29	4.42
Total	176	62.02	13.40	74	4.41

*General health scores were assessed on a six-point scale.

Table 2. Frequencies and percentages and their 95% confidence intervals of the patients with physical symptoms attributed to their high blood pressure.

Symptoms	Frequency	Percentage
Tiredness	54 (46-62)	31 (24-38)
Sudden hot flushes	49 (42-57)	28 ((21-35)
Headache	43 (36-51)	24 (18-31)
Reduced energy	41 (34-49)	23 (17-30)
Palpitations	39 (32-47)	22 (16-29)
Sudden sweating	36 (29-44)	21 (15-28)
Reduced physical performance	34 (28-42)	19 (14-26)
Dizziness	33 (27-41)	19 (14-26)
Shortness of breath	31 (27-41)	18 (13-24)
Pain in the chest	24 (18-31)	14 (10-20)
Sleeplessness	23 (17-30)	13 (9-19)
Blurred vision	16 (11-22)	9 (6-15)
Tinnitus	15 (10-21)	9 (6-15)
Increased muscle tension	10 (6-15)	6 (3-11)
Nausea	2 (0.6-6)	1 (0.01-3)
Sleepiness	-	-
Additional symptoms	6 (3-11)	3 (0.35-5)

Table 3. Percentage of the patients with daily emotional symptoms and situations they thought would increase their blood pressure.

	Percentage (95% CI)	Score of certainty (95% CI)
Emotional symptoms		
Anger	49 (42-57)	5.2 (2.6-9.6)
Frustrations	33 (26-40)	5.1 (2.5-9.5)
Psychic tension	48 (41-56)	5.1 (2.5-9.5)
Worry	31 (24-38)	5.0 (2.4-9.4)
Happiness	5 (2-9)	4.3 (1.9-8.6)
Sombreness	7 (4-12)	4.7 (2.1-8.9)
Relaxed feeling	5 (2-9)	4.9 (2.3-9.3)
Physiological symptoms of emotions		
Sweating	23 (17-30)	4.5 (1.9-8.6)
Increased heart rate	24 (18-31)	5.0 (2.4-9.4)
Fitness	5 (2-9)	4.7 (2.1-8.9)
Dizziness	18 (13-24)	4.6 (2.0-8.7)
Weakness	7 (4-12)	4.4 (1.9-8.6)
Nausea	8 (5-13)	4.8 (2.2-9.2)
Emotional situations		
During a busy day	24 (18-31)	4.8 (2.2-9.2)
After a busy day	22 (16-29)	4.8 (2.2-9.2)
Weekend	9 (5-14)	4.9 (2.3-9.3)
While awake at night	9 (5-14)	4.4 (1.9-8.6)
While sleeping	4 (2-8)	4.6 (2.0-8.7)
At daybreak	10 (6-15)	4.9 (2.3-9.3)
In the afternoon	14 (9-20)	4.6 (2.0-8.7)
In the evening	16 (14-25)	4.7 (2.1-8.9)

blood pressure, with an overall score of certainty of 4.8 (95% confidence interval of 4.7 to 4.9) on a six-point scale.

Cronbach's alpha for the outcome variable 'compliance status' was 0.79 (mean 6.69, SD (standard deviation) 1.19), for the indicator variables 4-7 (table 4) 0.70 (mean 6.65, SD 1.30), 0.87 (mean 5.92, SD 1.61), 0.80 (mean 3.42, SD 0.94), and 0.84 (mean 4.98, SD 2.30), respectively, indicating an adequate internal consistency and retest reliability of the test battery.

The patients were divided into two subgroups, those with low self-reported compliance (11 patients, 7 not taking their tablets at all and 4 not always taking them), and those with high self-reported compliance (165 patients). In order to assess whether there were differences in physical symptoms or social and psychological domains the two subgroups were compared with one another. The sample sizes of the two subgroups were unequal. However, Levene's test was not significant and, therefore, the variances of the two subgroups were not significantly different from one another. ANOVA modelling was thus adequate.

Table 4 gives an overview of the effects of the various physical, social and psychological factors on compliance. Scores of physical symptoms and social factors that might enhance non-compliance were not significantly higher in the non-adherers than they were in the adherers. The score of psychological factors, however, was significantly higher in the adherers than in the non-adherers at $p<0.018$, indicating that adherers more often felt dissatisfaction and guilt with the non-compliance status than did their non-compliant counterparts. There were also two trends to significance: daily emotional symptoms and situations were less frequent, and time factors were slightly more frequent in the adherers. The MANOVA of the last three variables showed the overall existence of a significant difference in the data at $p<0.012$. This difference was mainly due to the score of the psychological factors (table 5). However, the above trends in the emotional symptoms and time factors domain remained, even after adjustment for multiple testing.

Discussion

The above results give rise to some relevant conclusions. First, psychological factors are the most important determinants of compliance. Patients who lack feelings of dissatisfaction and guilt about being non-compliant have the highest risk of being non-compliant. This finding is consistent with published results from others.[12] Physical symptoms and social factors as contributors to non-compliance have not been widely

Table 4. Comparison of mean scores of physical symptoms (1-3), and social and psychological domains (4-7) in patients with low and those with high compliance (n=number of patients).

	Indicator variables	Adherer	Non-adherer	N	F value	P value
1	Physical symptoms due to hypertension	2.590	3.570	169	1.077	0.301
2	Numbers of daily emotional symptoms and situations increasing blood pressures	3.740	6.290	167	2.449	0.120
3	Scores of certainty of the above daily situations	4.822	5.082	123	0.384	0.537
4	Experienced difficulties with being compliant	6.641	6.429	165	0.242	0.623
5	Social factors causing non-compliance	5.944	5.605	163	0.411	0.522
6	Time factors causing non-compliance	3.473	2.893	162	3.870	0.051
7	Psychological factors causing non-compliance	5.052	3.056	163	5.702	0.018

Table 5. Overall assessment of the indicator variables from table 4 with p values <0.15, using MANOVA and multiple comparison adjustment according to the Games-Howell procedure (n=number of patients).

	Indicator variables	Adherer	Non-adherer	N	F value	P value
2	Numbers of daily emotional symptoms and situations increasing blood pressure	3.830	7.000	155	3.179	0.077
6	Time factors causing non-compliance	3.465	2.958	155	2.559	0.112
7	Psychological factors causing non-compliance	5.096	3.056	155	6.139	0.014

studied so far. The current study shows that they were not significant contributors to the level of compliance. Patients with many physical symptoms were not more compliant than were patients with few symptoms. There was even a trend towards better compliance in the patients with few daily emotional symptoms and situations. We have no explanation for this unexpected finding. But a chance finding is of course a possible explanation. The same may be true for the effects of time factors causing non-compliance. We recommend that when dealing with their patients' compliance physicians do not emphasise the physical symptoms that may result from being non-compliant, but rather focus on lack of feelings of guilt, regret and shame in non-adherers. Some education and a somewhat annoyed doctor might do them good.

A limitation of our study was the small number of non-compliant patients in our sample. This may be due to the fact that all of the patients were being treated by specialists rather than generalists. The conclusions of this study should, therefore, not be routinely applied to patients treated by generalists. Another limitation is the large proportion of patients who were invited but preferred not to participate, over 60%. This may have introduced some selection bias.

Conclusions

The effect of physical symptoms on non-compliance in mildly hypertensive patients is negligible. So is the effect of social factors. Psychological factors such as a lack of a sense of guilt, regret and shame are major determinants of non-compliance. Physicians may play an educational role in improving their patients' compliance by addressing these determinants. ■

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